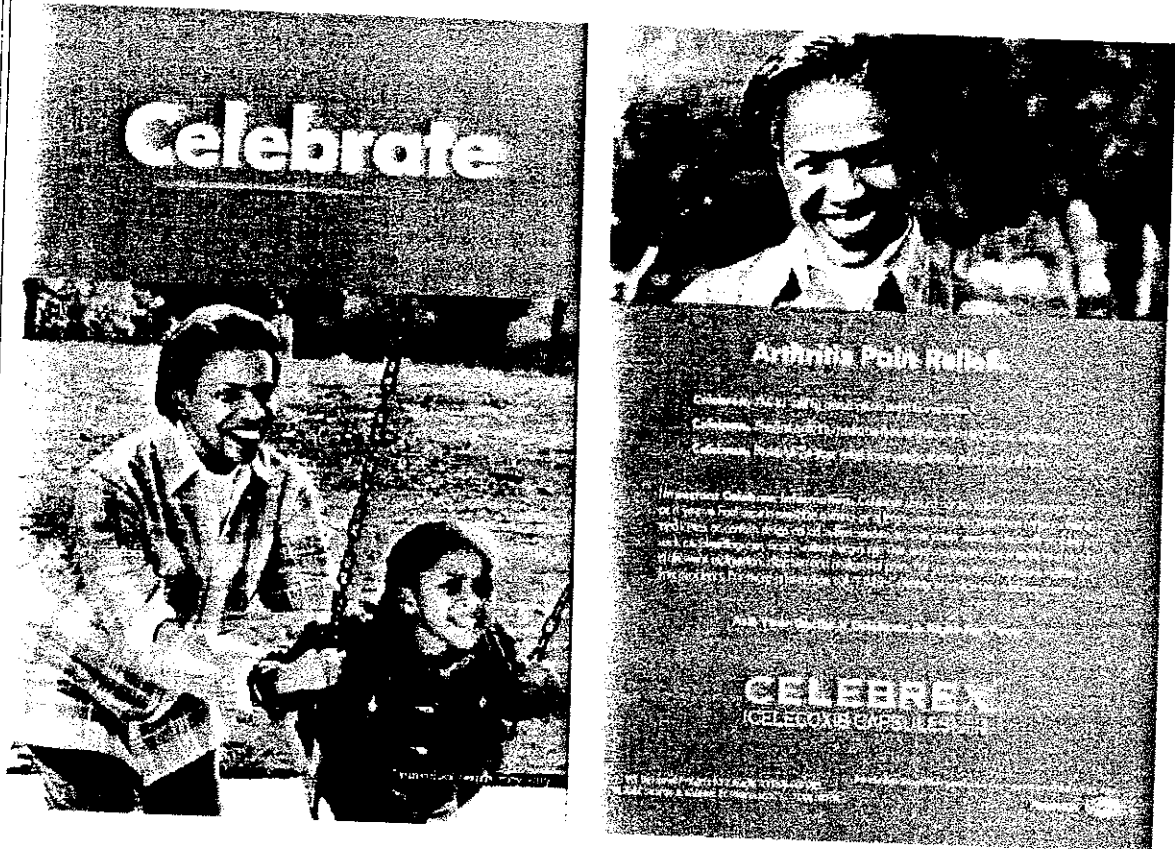
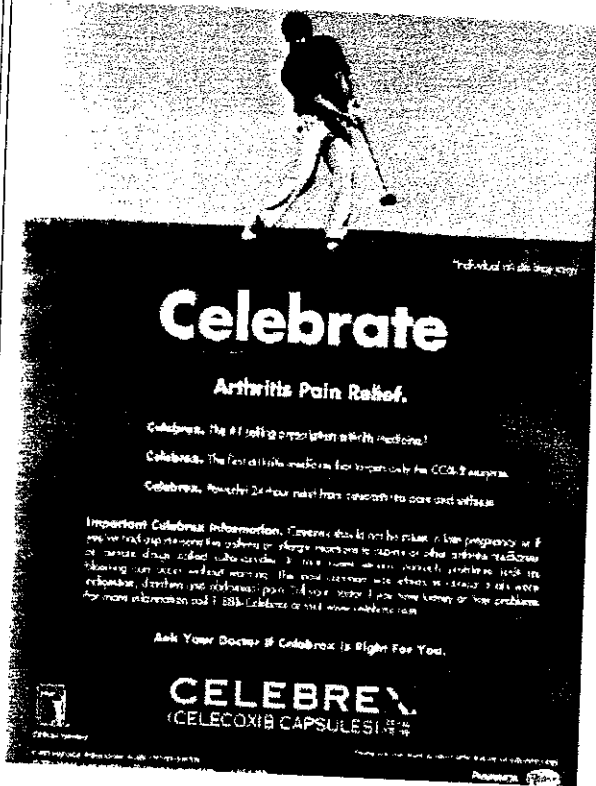


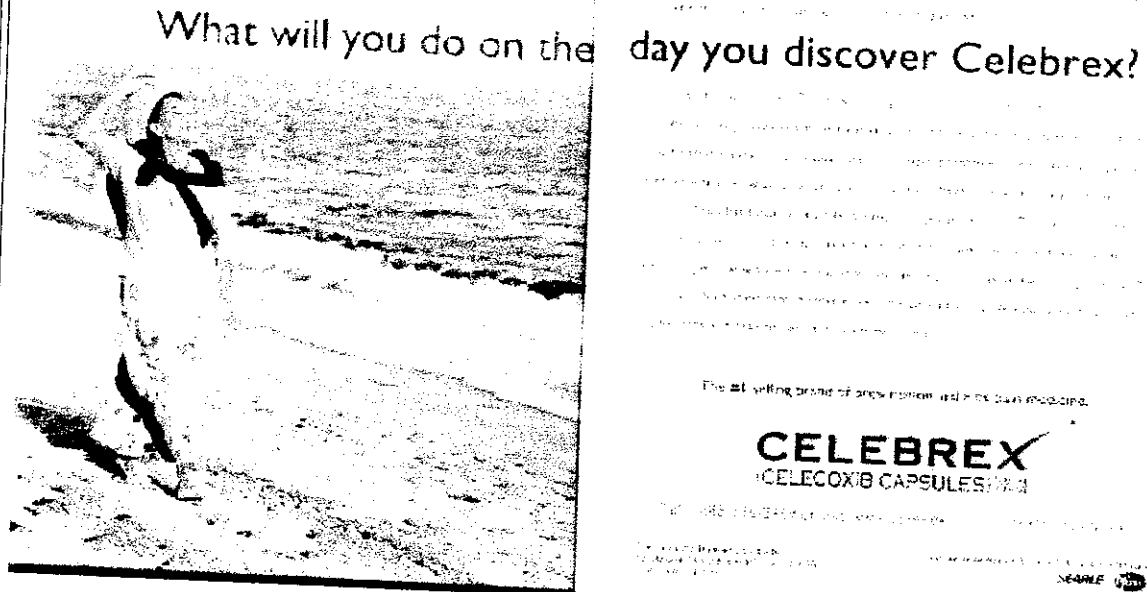
175. This advertisement which ran during January 2001 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. By stating that it is the "first arthritis medicine that targets only the COX-2 enzyme" it wrongly implies that it is superior to other NSAIDs and fails to disclose the cardiovascular risks associated with Celebrex.



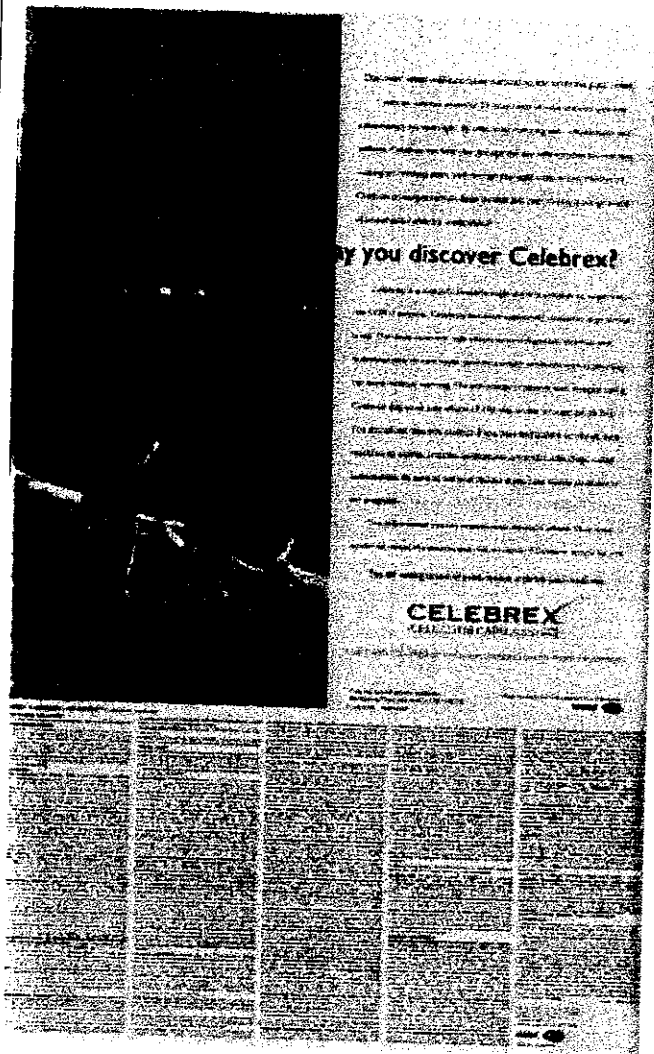
176. This advertisement which ran during June 2001 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims and fails to disclose the cardiovascular risks associated with Celebrex. By stating that it is the "first arthritis medicine that targets only the COX-2 enzyme" it falsely implies that it is superior to other NSAIDs.



177. This advertisement which ran during May 2001 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims without disclosure of the cardiovascular risks associated with Celebrex. By stating that it is the "first arthritis medicine that targets only the COX-2 enzyme" it falsely implies that it is superior to other NSAIDs.



178. This advertisement which ran during February 2000 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims and fails to disclose the cardiovascular risks associated with its use. The advertisement claims that Celebrex is a "breakthrough" falsely implying that it is superior to other NSAIDs.



179. This advertisement which ran during September 1999 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims and fails to disclose cardiovascular risks. The advertisement claims that Celebrex is a "breakthrough" falsely implying that it is superior to other NSAIDs.

With Celebrex, I will play the long version.

One pill. 24 hours.
If you've been managing the joint
pain of osteoarthritis on your own, it
might be time to ask your doctor about
CELEBREX. Just one CELEBREX
provides up to 24 hours of relief from joint
pain, inflammation and stiffness. So next
time you play, you can play the long version.

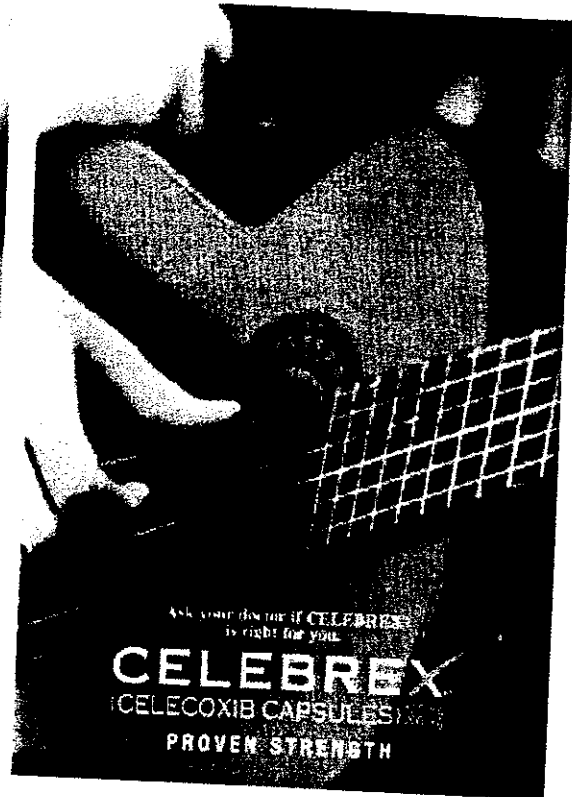
Take control of your joint pain with
CELEBREX. Call your doctor, or call
1-888-CELEBREX (235-3273).
www.celebrex.com

CELEBREX should not be taken if you've
had aspirin-sensitive asthma or allergic reactions
due to aspirin or other salicylate medicines or
certain drugs called sulfonamides. In rare cases,
serious stomach problems such as bleeding
can occur without warning. Tell your doctor
if you have kidney or liver problems.

*Please see important product
information on adjacent page.*

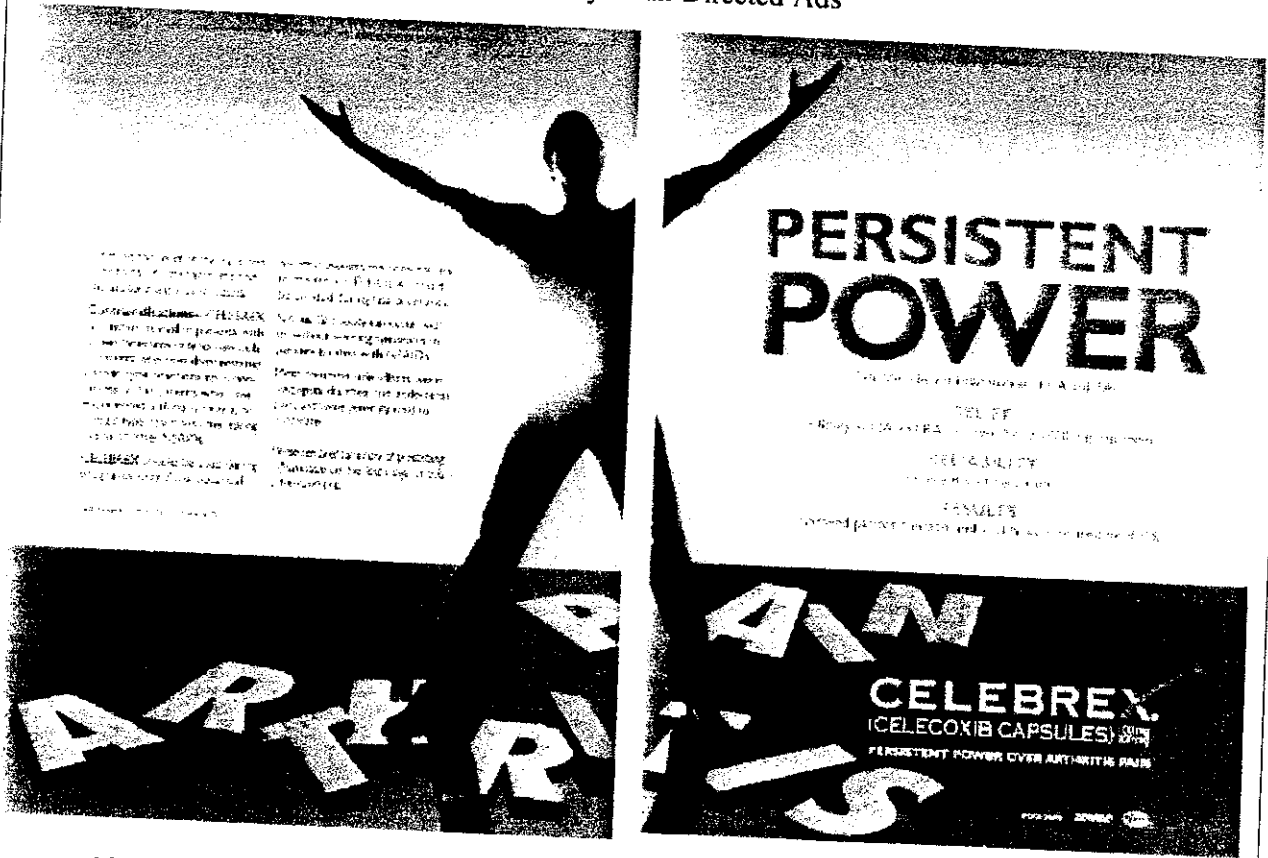


© 2004 Pfizer Corporation, Inc.

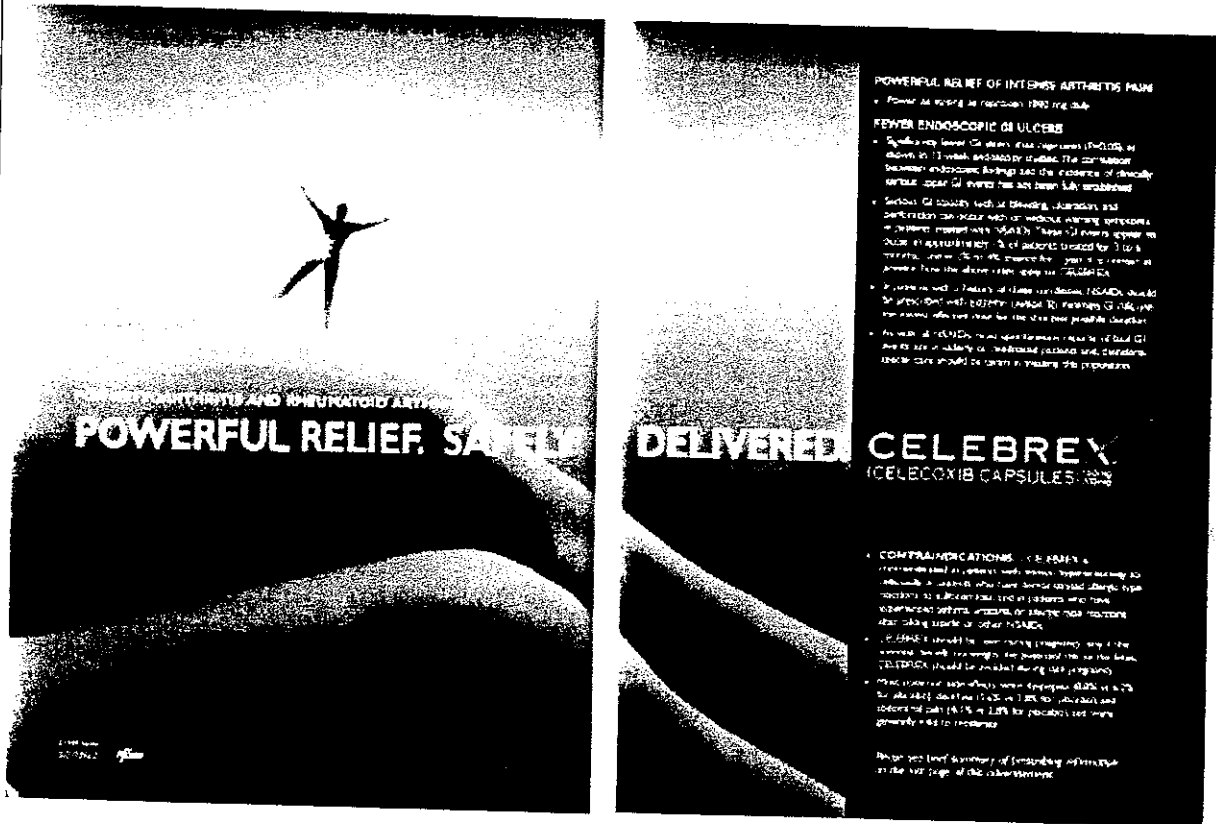


180. This advertisement which ran during July 2004 overstates the effectiveness of Celebrex and the FDA warned Defendants that it was misleading, for failure to disclose risk information, and for overstating the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials.

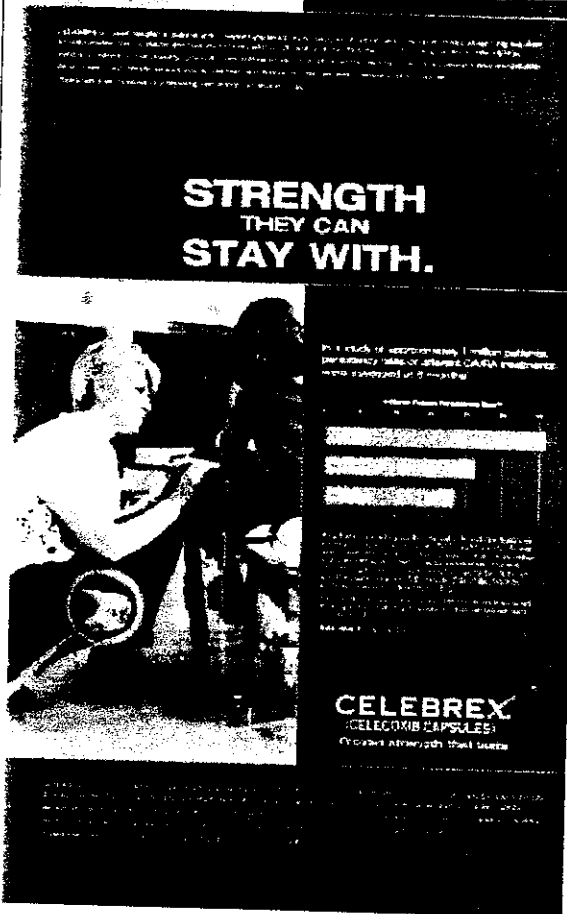
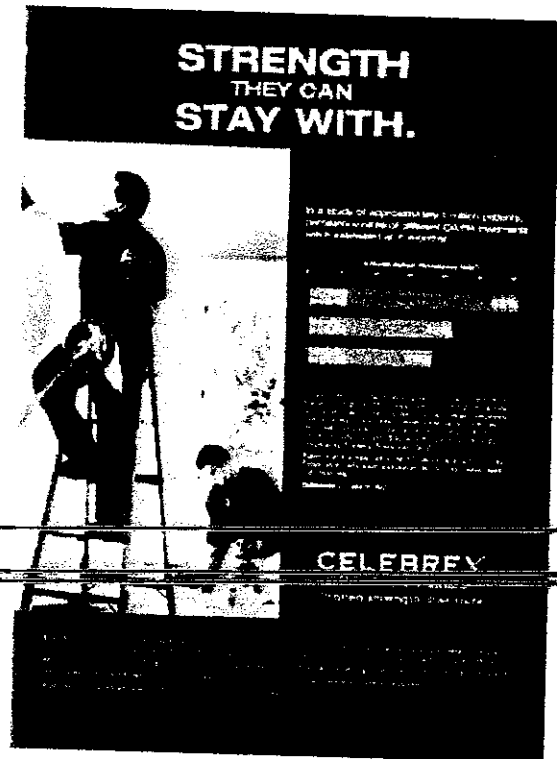
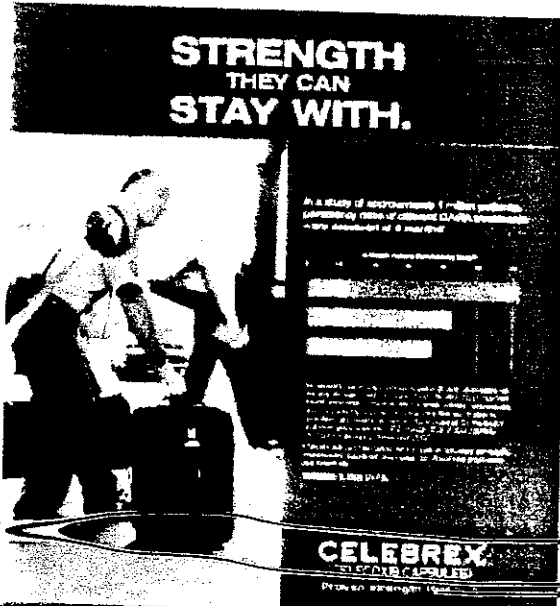
Celebrex Physician Directed Ads



181. This advertisement which ran during July 2000 makes unsubstantiated superiority claims. By comparing the effectiveness of Celebrex to naproxen the advertisement falsely implies that it is superior to other NSAIDs. The statement "Excellent GI tolerability" is false and misleading, particularly in light of the reference to GI complications for NSAIDs with no such mention of complications for Celebrex. Further, Celebrex did not show excellent GI tolerability. Rather, its tolerability was no different than NSAIDs and in fact the CLASS study showed increased complications from Celebrex.



182. This advertisement which ran during November 1999 makes unsubstantiated superiority claims. By comparing the effectiveness of Celebrex to naproxen the advertisement falsely implies that it is superior to other NSAIDs, and falsely claims that there are “significantly fewer GI ulcers” when in fact this is not statistically proven. This advertisement is misleading by referring to significantly lower endoscopic ulcers, which were found by the FDA not to be significant and is further misleading for the failure to balance that statement with the FDA finding that Celebrex was not better in safety than NSAIDs. In addition, by referring to NSAIDs and GI complications without reference to Celebrex and GI complications the advertisement is unbalanced and misleading.



183. The above three advertisements which ran during February and March 2004 are misleading. In a letter to Pfizer the FDA stated: "The print ad features the prominent headline

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1 "Strength They Can Stay With" and shows a chart comparing Celebrex, Ibuprofen and Naproxen,
2 titled "6-Month Patient Persistency Rate." Over the chart is the statement, "In a study of
3 approximately 1 million patients, persistency rates of different OA/RA treatments were assessed at
4 6 months." The tagline below the Celebrex logo in the print ad is "Proven strength that lasts."

5 184. In the letter to Pfizer the FDA stated: "The above referenced claims imply that
6 Celebrex is more effective (*i.e.*, stronger) than ibuprofen and naproxen for treatment of
7 osteoarthritis or rheumatoid arthritis and that patients 'stay with' or are more compliant with
8 Celebrex therapy than the compared products. We are not aware of substantial evidence or
9 substantial clinical experience to support these claims. The cited retrospective retail pharmacy

10 database analyses by NDC Health, 'Persistency Analysis: Celebrex, Vioxx, and All Other
11 NSAIDs,' August 2002 and 'Persistency Analysis: Celebrex, Vioxx, Ibuprofen, and Naproxen,'
12 from November 2002 (almost two years ago), do not contain any data or information
13 demonstrating that patients found Celebrex to be more effective than the other products, or that
14 patients will be more 'persistent' or compliant with Celebrex therapy. Moreover, the database
15 information did not note the indication for which the drug was prescribed, so the suggestion that
16 these rates reflect specifically OA/RA patients is misleading. In addition, the analyses do not
17 account for factors that affect persistence or compliance such as cost insurance coverage, side
18 effects, dosage regimen, and ease of use. Therefore, the analyses do not constitute substantial
19 evidence or substantial clinical experience demonstrating that OA/RA patients are more compliant
20 with Celebrex or stay on Celebrex longer because it is more effective than other products for the
21 treatment of OA or RA."

22 **J. Concealment of Cardiovascular Risks and Dangers**

23 185. The CLASS study published in 2000 assessed the incidence of clinically significant
24 upper GI events seen over one year of treatment with Celebrex compared to ibuprofen and
25 diclofenac. A post-hoc analysis was done between those patients taking low-dose aspirin for
26 cardiac protection and those patients not taking low-dose aspirin. The published article found that
27 the incidence of cerebrovascular accident, myocardial infarction, and angina was not statistically
28

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1 different between patients taking the three drugs. However, the published data only reflected a 6-
2 month period used by the company to espouse an unsupportable claim of decreased GI toxicity.

3 186. The 12-month data set available from the FDA revealed that the rate of combined
4 anginal adverse events was 1.4% in the celecoxib group versus 1.0% in either NSAID group, a
5 non-statistically significant difference. However, this tendency toward increased cardiovascular
6 toxicity was described by the FDA Medical Officer Dr. Witter, "For anginal disorders (especially
7 the combined disorders), *there seems to be a trend toward more [cardiac adverse] events in those*
8 *patients receiving celecoxib*, regardless of aspirin use." Had the results of the study completed in
9 1999 been available to the FDA Medical Officer, they surely would have given this finding greater

10 significance.

11 187. This trend was *magnified* in those patients not taking low-dose aspirin. Combined
12 anginal disorders were increased in these patients; the celecoxib group had 0.6% vs. 0.2% and 0%
13 in the diclofenac and ibuprofen groups, respectively. There were also more combined atrial serious
14 cardiac adverse events with celecoxib, 0.3% compared to 0.1% and 0% in the diclofenac and
15 ibuprofen groups, respectively. Dr. Witter commented, "In the non-aspirin users, there appears to
16 be a slight trend toward more [serious cardiac adverse] events in those patients receiving celecoxib
17 for combined atrial and anginal disorders." Additionally, the rate of myocardial infarction was
18 higher in the celecoxib group, 0.2%, compared with the other two drugs, 0.1%. Dr. Witter also
19 referred to data from the original NDA for celecoxib in his discussion, "There were suggestions of
20 a dose-response relationship (...100mg BID celecoxib, 0% crude mortality rate vs. 400 mg BID
21 celecoxib, 0.64% crude mortality rate) between cardiovascular mortality and [increased] celecoxib
22 use that could not be adequately addressed by the data."

23 188. The FDA was concerned enough that they ordered a cardiorenal consult by Medical
24 Officer Dr. Throckmorton on the same CLASS study data. In his report he noted, "The CLASS
25 trial data do not support a large adverse effect of celecoxib on cardiovascular mortality or on
26 serious adverse events related to thrombosis relative to either diclofenac or ibuprofen. The data do
27

1 not exclude a less apparent pro-thrombotic effect of celecoxib, such as might be reflected in the
2 relative rates of cardiac adverse events related to ischemia.”

3 189. While none of the CLASS data was statistically significant, they revealed a
4 consistent and worrisome trend toward increased cardiovascular toxicity, particularly that related to
5 increased thrombosis.

6 190. The reviewers’ recommendations were, “Our findings suggest a potential increase in
7 cardiovascular event rates for the presently available COX-2 inhibitors ... definitive evidence of
8 such an adverse effect will require a prospective randomized clinical trial Given the
9 remarkable exposure and popularity of this new class of medications, we believe that it is
10 mandatory to conduct a trial specifically assessing cardiovascular risk and benefit of these agents.

11 Until then, we urge caution in prescribing these agents to patients at risk for cardiovascular
12 morbidity.” Although employing a placebo group from a different trial weakens the validity of
13 their analysis, the author’s call for a prospective randomized clinical trial powered to truly analyze
14 the cardiovascular risk to benefit ratio was then exactly correct. Recently, however, such a
15 placebo-controlled trial of celecoxib has clearly demonstrated this risk (as did the study that was
16 completed in 1999, but not disclosed to the FDA in a timely fashion).

17 191. This trial was the APC colon polyprecurrence prevention study, in which
18 approximately 2,000 patients took celecoxib or a placebo. Interestingly, this was the longest
19 celecoxib trial to date with a mean duration of treatment being 33 months as opposed to the much
20 shorter 12-month duration of the CLASS study. A statistically significant elevation in the risk for a
21 major fatal or non-fatal cardiovascular event (a composite endpoint of cardiovascular death, acute
22 myocardial infarction, and stroke) was seen in those patients taking celecoxib compared to those in
23 the placebo group. This followed a dose-response relationship: the relative risk at 400mg/day of
24 celecoxib was 2.5 while the relative risk at 800mg/day was 3.4. Because of this unacceptable
25 danger, the trial was prematurely halted. The FDA released an explanatory statement which said,
26 “While we have not seen all available data on Celebrex, these findings are similar to recent results
27
28

1 from a study of Vioxx (rofecoxib), another drug in the same class as Celebrex. Vioxx was recently
2 voluntarily withdrawn by Merck.”

3 192. Given the above data and trends, advertising, promotional and other materials,
4 promoting the safety of Celebrex was misleading. This trend and the omission of material facts in
5 Defendants’ promotional materials are more alarming in view of a 1999 study that was unpublished
6 that showed patients taking Celebrex were more likely than those taking a placebo to have heart
7 attacks. Though the study was small, its conclusions contradicted years of claims by Defendants
8 that no trial of Celebrex had ever shown adverse cardiac results. Plus, when combined with the
9 CLASS results, this clearly raised a red flag as to risks that physicians should have been made
10 aware of.

11 193. Each of the foregoing advertisements also failed to disclose the increased risk of
12 heart problems that were known to Defendants at the time Celebrex was launched. Defendants
13 concealed until recently a study completed June 24, 1999 comparing Celebrex to placebo for the
14 slowing of the progression of Alzheimer’s Disease and overall safety. Patients taking Celebrex
15 were 3.6 times more likely to experience a serious cardiovascular event (2.1% of patients taking
16 placebo vs. 7.7% of patients taking Celebrex).⁸ Pfizer’s report of this study shows that the
17 increased risk of cardiovascular complications in patients taking Celebrex was statistically
18 significant.⁹ Furthermore, among patients taking Celebrex there were 12% more serious adverse
19 events (25.6% vs. 22.9%) and 59% more deaths (4.6% vs. 2.9%). The study was never published
20 and was not presented to the FDA in time to be included in the February 2001 Advisory Committee
21 Meeting that considered the safety of Celebrex. Had the findings from this study been published
22 and disclosed to the FDA in a timely manner, sales of Celebrex — based primarily on the claimed
23 safety advantage over older, less expensive NSAIDs — would have been dramatically less. These
24

25 ⁸ Letter to FDA revealing heart dangers in an unpublished clinical trial of Celebrex (HRG Publication #1721),
Public Citizen, January 31, 2005. <http://citizen.org/publications/release.cfm?ID=7359>

26 ⁹ A statistically significant difference favoring placebo in adverse events was observed for certain CV-related body
27 system terms (Cardiovascular Disorders, General; Heart Rate and Rhythm Disorders; Myo, Endo, Pericardial & Valve
Disorders). These differences were primarily driven by the individual terms cardiac failure, fibrillation atrial, and
angina pectoris. http://www.clinicalstudyresults.org/documents/company-study_76_0.pdf

findings would have been of singular importance to prescribing doctors given the concern, appropriately express in the JAMA article reporting the first six months of the CLASS study, about the theoretical risk of increased adverse events disturbing the clotting balance with selective COX-2 inhibition:

Although it has been hypothesized that COX-2-specific inhibitors might increase the risk of cardiovascular thromboembolic events via inhibition of vascular prostacyclin synthesis without a corresponding inhibition of platelet thromboxane, no such increase was evident in the current study.

Pharmacia's failure to make the results of this study available are particularly vexing, because it was completed eight months before the CLASS study was completed, and it's results should have informed the report published in JAMA.

194. Defendants' 1999 results as to the cardiovascular risks presented by Celebrex were confirmed in a study relayed by New Zealand's Medical Research Institute, which found that patients taking Celebrex had a cardiovascular risk as great as those taking Vioxx.

195. The concealment of cardiovascular risks was evidenced by a letter sent to the FDA on January 31, 2005:

January 31, 2005

Dr. Lester M. Crawford, Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Crawford,

Since filing our petition last week (January 24th) to immediately ban celecoxib (Celebrex) and valdecoxib (Bextra)[1] *we have discovered the results of an unpublished randomized placebo-controlled study of Pfizer*, finished more than four years ago, that showed a significantly increased rate (3.5-fold) of serious cardiovascular adverse events and *more than a doubling in the rate of cardiovascular deaths in people using celecoxib compared to those using a placebo in a study concerning Alzheimer's disease.* (Emphasis added.)

* * *

1 The combined rate of all serious cardiovascular adverse events in
2 patients getting a placebo was 2.1% but was greatly increased in
3 those getting celecoxib to 7.7%, a 3.6-fold increase in cardiovascular
4 risk in those people taking celecoxib. (p=0.03)

5 * * *

6 Thus, there was a statistically significant increase in the composite of
7 all serious cardiovascular events in patients getting Celebrex
8 compared to patients getting a placebo.

9 196. Defendants concealed this study because its publication would have impacted the
10 marketing and pricing of Celebrex and its use by Class Members. Since its "Black Box" warning
11 concerning cardiovascular risks issued in August 2005, which constitutes only a partial disclosure,
12 Celebrex sales have dropped by 48%.

13 **K. Pfizer Temporarily Halts the Celebrex Promotional Scheme**

14 197. On or about September 30, 2004, Merck withdrew its COX-2 inhibitor, Vioxx from
15 the marketplace. In response, Pfizer issued a statement indicating it was "confident in the long
16 term cardiovascular safety of Celebrex" and indicated that "since the introduction of COX-2
17 inhibitors, the rate of hospitalizations for gastrointestinal events associated with long term arthritis
18 treatment has declined significantly."

19 198. The foregoing statement was misleading in that it failed to show the existence of
20 reliable studies indicating that Celebrex did present cardiovascular risks and there was no
21 statistically significant evidence to support the claim that Celebrex or other COX-2 inhibitors lead
22 to a decrease in serious GI complications. In fact, data from a Canadian study shows that after
23 COX-2 inhibitors became available in 2000 there was a 41% increase in NSAID use (accounted for
24 entirely by COX-2 inhibitors) and a 10% increase in the hospitalization rate for GI bleeding –
25 belying the claim above.¹⁰

26 199. On December 17, 2004, Pfizer shocked consumers by disclosing a study that
27 demonstrated an increased risk of cardiovascular disease (the 1999 study referred to above). Pfizer
28

¹⁰ Mamdani M., Juurlink D.N., Kopp A., et al., Gastrointestinal bleeding after the introduction of COX-2
inhibitors: ecological study, *British Medical Journal Online*:
<http://bmj.bmjjournals.com/cgi/reprint/bmj.38068.716262.F7v1>

1 then announced on December 20, 2004, that it would stop all television, radio, newspaper and
2 magazine advertising. Pfizer did so because it was aware that its previous campaign was
3 misleading.

4 200. On February 1, 2005, Pfizer finally admitted it was aware of the 1999 clinical trial
5 finding that elderly patients using Celebrex were far more likely to suffer heart problems than
6 patients taking a placebo. The study was never published and was not submitted to the FDA until
7 2001, four months after the FDA's review of Celebrex and Vioxx. An FDA reviewer who was
8 unaware of the study has stated that had the Panel known about this study, it might have acted
9 differently on Celebrex prior to August 2005. Celebrex, unlike Vioxx, was not required by the
10 FDA to carry warnings of cardiovascular risk. The lack of warning is a main reason why Celebrex
11 has achieved greater commercial success than Vioxx.

12 **L. Defendants' Continued Unlawful Marketing Campaign Caused Active Concealment**
13 **of Celebrex's Deficiencies and Over Payments by End-Payers for Celebrex**

14 201. As a result of Merck's claims, Plaintiffs and members of the Class purchased and/or
15 paid for Celebrex even though a monthly supply was much more expensive than other NSAIDs.

16 202. To justify the disparity of Celebrex's pricing as compared to other NSAIDs and to
17 ensure that physicians would prescribe and that End-Payers would purchase and pay for the drug,
18 Celebrex misrepresented the safety and efficacy of Celebrex and omitted, concealed and
19 suppressed the risks, dangers, and disadvantages of the drug. Consequently, Celebrex captured a
20 large market share of anti-inflammatory drugs prescribed for and used by patients. In 2004 alone,
21 sales of Celebrex exceeded \$1.2 billion, despite the significantly higher cost of Celebrex as
22 compared to other pain relievers in the same family of drugs.

23 203. Celebrex's deceptive and misleading marketing campaign concealed, omitted, and
24 suppressed information that resulted in overcharges to consumers and Third-Party Payors, such as
25 Plaintiffs and the Class, for, in whole or in part, the costs of Celebrex. Millions of End-Payers,
26 including consumers and Third-Party Payors, have already paid for, and/or purchased and
27 consumed Celebrex at prices based on the proposed wholesale price, which was about one hundred
28 times the cost of a generic aspirin. These End-Payers did not get the benefit of the bargain that

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1 Defendants held out to them and as a result End-Payors paid more than they would have or should
2 have because Celebrex was promoted and advertised as a premium drug with reduced side effects
3 for the purpose of deceiving consumers and End-Payors about Celebrex's adverse cardiovascular,
4 and GI effects.

5 V. FRAUDULENT CONCEALMENT

6 204. Throughout the Class Period, Defendants affirmatively and fraudulently concealed
7 its unlawful conduct from Plaintiffs and the Class.

8 205. Plaintiffs and the Class did not discover, and could not discover through the exercise
9 of reasonable diligence, that Defendants had unlawfully concealed, omitted, and suppressed the
10 serious adverse effects of Celebrex. Defendants conducted its unlawful activities in secret,
11 concealed the nature of their unlawful conduct, and attempted to confine information concerning
12 the adverse effects of Celebrex. Defendants attempted to withhold such information from Plaintiffs
13 and members of the Class, the medical community, regulators and the public. Defendants
14 fraudulently concealed its activities through various means and methods designed to avoid
15 detection.

16 206. Plaintiffs and the Class could not have discovered Defendants' unlawful conduct at
17 an earlier date through the exercise of reasonable diligence because Defendants actively and
18 purposefully concealed their unlawful activities.

19 207. Defendants engaged in a successful, illegal fraud on consumers, Third-Party Payors
20 and the general public, by which they deliberately and affirmatively concealed material
21 information on the risks, dangers, defects, and disadvantages of Celebrex, in at least the following
22 respects:

23 a. By failing to disclose adverse effects of Celebrex to Plaintiffs, the Class, the
24 medical community, regulators, and the public;

25 b. By failing to warn Plaintiffs, the Class, the medical community, regulators,
26 and the public of those adverse effects;

c. By agreements among senior Pfizer and Pharmacia officials in meetings and in communications not to discuss publicly, or otherwise reveal, the totality of the adverse effects caused by Celebrex, Defendants' concealment of those adverse effects, and the nature and substance of other acts and communications in furtherance of Defendants' illegal scheme; and

d. By concealing studies showing increased risk of cardiovascular disease.

208. As a result of Defendants' fraudulent concealment, Plaintiffs and the Class purchased and/or paid for Celebrex and could not reasonably have discovered Defendants' misconduct regarding Celebrex prior to April 7, 2005. Plaintiffs and the Class therefore assert the tolling of any applicable statute of limitations affecting the rights of action of Plaintiffs and the Class.

VI. CLASS ACTION ALLEGATIONS

209. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, Plaintiffs seek certification of a national Class defined as follows:

All End-Payers located in the United States, including Consumers and Third-Party Payers,¹¹ who purchased and/or paid for Celebrex not for resale during the period from December 1, 1998 through the present.

Excluded from the proposed Class are (i) Defendants, any entity in which Defendants have a controlling interest or which have a controlling interest in Defendants, and Defendants' legal representatives, predecessors, successors and assigns; (ii) the judicial officers to whom this case is assigned; and (iii) any member of the immediate families of excluded persons, (iv) governmental agencies, and (v) those who resold Celebrex.¹²

210. Plaintiffs also define state law subclasses as defined in the various courts set forth below.

¹¹ Third-Party Payers include all entities that: (a) provide, sponsor or insure a healthcare plan, which includes prescription drug coverage to natural persons, and (b) purchase, pay or insure all or part of the cost of prescription drugs prescribed and dispensed to those persons pursuant to a health plan.

¹² Plaintiffs have named class representatives for the Class, but have not named class representatives for every jurisdiction. Should the Court so require or direct, Plaintiffs are prepared to name proposed class representative Plaintiffs for every jurisdiction, or for each statewide class, and for each subclass the Court may designate.

1 211. The members of the Class are so numerous that joinder of all their members would
2 be impractical. Celebrex has been prescribed to, paid for and ingested by millions of consumers
3 nationwide.

4 212. There are questions of law and fact common to the Class that predominate over
5 questions affecting only individual members, including, but not limited to:

- 6 a. Whether Defendants engaged in a fraudulent and/or deceptive scheme to
7 portray Celebrex as a drug having superior qualities to other NSAIDs;
8 b. Whether Defendants engaged in a scheme to create consumer demand for
9 Celebrex based on deceptive statements concerning Celebrex's safety and efficacy;
10 c. Whether as a result of this scheme Celebrex was over prescribed;
11 d. Whether the price of Celebrex was inflated as a result of the scheme;
12 e. Whether Defendants formed an enterprise for the purposes of carrying out
13 the scheme;
14 f. Whether Defendants used the U.S. mails and wires to facilitate the scheme;
15 g. Whether Defendants' conduct violated RICO;
16 h. Whether Defendants are liable to Plaintiffs and the Class for damages under
17 state consumer protection statutes;
18 i. Whether Defendants made material misrepresentations or material omissions
19 about the cardiovascular risks associated with using Celebrex and regarding the
20 effectiveness of Celebrex; and
21 j. Whether members of the Class are entitled to damages based on their
22 payments for Celebrex, and, if so, the nature and amount of such damages.

23 213. Plaintiffs' claims and defenses are typical of the claims and defenses belonging to
24 absent members of the Class, because Defendants have uniformly misrepresented that Celebrex is
25 safer and more effective than traditional NSAIDs, overpromoted the benefits of Celebrex and
26 uniformly failed to disclose the material cardiovascular risks associated with Celebrex.
27

1 Defendants' actions have deprived Plaintiffs and the members of the Class of their ability to make
2 an informed decision about whether to pay for Celebrex, and if so at what price.

3 214. Plaintiffs will fairly and adequately assert and protect the interests of absent
4 members of the Class, because Plaintiffs have retained counsel competent and experienced in
5 complex class action litigation and have no interest adverse to any absent Class Members.

6 215. Class certification is proper under Federal Rule of Civil Procedure 23(b)(1)(A),
7 because the prosecution of separate actions by individual Class Members would create a risk of
8 inconsistent or varying adjudications with respect to individual members of the Class and establish
9 incompatible standards of conduct for Defendants.

10 216. Class certification is proper under Federal Rule of Civil Procedure 23(b)(1)(B),
11 because the prosecution of separate actions by individual Class Members would create a risk of
12 adjudications with respects to individual Class Members which would, as a practical matter, be
13 dispositive of the interest of the other members not parties to these adjudications and/or
14 substantially impair their ability to protect these interests.

15 217. Class certification is proper under Federal Rule of Civil Procedure 23(b)(2), because
16 Defendants have acted, or refused to act, on grounds generally applicable to the Class, thereby
17 making final injunctive relief or corresponding declaratory relief appropriate for the Class.

18 218. Class certification is proper under Federal Rule of Civil Procedure 23(b)(3), because
19 common issues of law and fact predominate over any questions affecting only individual members
20 of the Class, and a class action is superior to other available methods for the fair and efficient
21 adjudication of this controversy.

22 219. The need for Class-wide notice does not provide a barrier to certification, in that
23 notice can be effectively disseminated to Class by techniques customarily used in consumer class
24 actions, including published notice, Internet notice and direct mailings based on readily available
25 computer databases (such as the one Defendants used to send their "Dear Patient" correspondence).
26
27
28

FIRST CLAIM FOR RELIEF
(Violations of 18 U.S.C. § 1962(c))

220. Plaintiffs incorporate by reference the preceding paragraphs as if they were fully set forth herein.

221. This claim, which alleges violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), is asserted against Defendants on behalf of the Class.

222. Plaintiffs, the members of the Class, and Defendants are each "persons," as that term is defined in 18 U.S.C. § 1961(3).

223. At all relevant times, in violation of 18 U.S.C. § 1962(c), Defendants conducted the affairs of an association-in-fact enterprise identified herein, the affairs of which affected interstate commerce through a pattern of racketeering activity.

Celebrex Enterprise

224. For purposes of this claim, the RICO "enterprise" is an association-in-fact consisting of each of the Defendants, including their directors, employees and agents and includes outside advertising agencies utilized by Defendants and the Medical Directors of Searle and Pfizer. While maintaining their separate legal identities and titles, each of these entities and persons joined together to run the Enterprise. The association-in-fact is referred to herein as the "Celebrex Enterprise." At all relevant times, the Celebrex Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of (a) publishing or otherwise disseminating information about Celebrex, which all too often included disseminating false and misleading information for the purpose of trying to make Celebrex a blockbuster drug, (b) jointly presenting data to the FDA and other medical journals that is misleading and/or has been manipulated to distort the results of clinical trials, (c) selling, promoting, and distributing Celebrex to Plaintiffs and Class Members, (d) achieving as a goal breaking the NSAID barrier, *i.e.*, having Celebrex replace NSAIDs as the preferred treatment, and (e) deriving profits from these activities beyond those that could have been attained without operation of the Celebrex Enterprise. The Celebrex Enterprise had as a common purpose creating a demand for Celebrex in a class of consumers who could have used NSAIDs and

516090.1

1 achieved the same pain relief at a lower cost. Defendants have this as a purpose because without
2 the Celebrex Enterprise, they would not be able to sell Celebrex at the prices at which it was sold.
3 During most of the time relevant to this Complaint, each Defendant maintained a separate legal
4 identity while operating the Celebrex Enterprise and others associated with and part of the
5 Celebrex Enterprise maintained their separate identities. The Celebrex Enterprise continues to
6 operate through Pfizer and through the instructions it issues to its agents for the purpose of carrying
7 out the objectives of the Celebrex Enterprise. Agents and members of the Celebrex Enterprise
8 include advertising agencies used to create Celebrex advertisements and doctors who co-author
9 articles promoting the efficacy of Celebrex. As to each Defendant, the association-in-fact met on a
10 regular basis to discuss the operations of the Celebrex Enterprise and the Celebrex Enterprise's
11 efforts were coordinated and agreed to by each Defendant.

12 225. Each of the members of the Celebrex Enterprise had a systemic linkage, because
13 there are contractual relationships, financial ties and continuing coordination of activities between
14 the Defendants and the Celebrex Enterprise. As to each Defendant, there was a common
15 communication network by which information concerning the Celebrex Enterprise was exchanged
16 on a regular basis. Typically this communication occurred by the use of electronic mail or the
17 telephone in which Defendants planned the operation of the Celebrex Enterprise alleged herein and
18 ran its continuing operation.

19 226. As part of their conduct of the Celebrex Enterprise and as part of the Enterprise's
20 decisional marketing structure, Defendants agreed to maintain close communication between
21 scientists at each company who were studying safety and efficacy, agreed to control media access
22 to safety news and to provide each company's sales force with an agreed response to safety issues.
23 Defendants also agreed to issue jointly sponsored advertisements that furthered the purposes of the
24 Celebrex Enterprise.

25 227. With the merger of Pfizer and Pharmacia and the purchase of Searle by Pharmacia,
26 the Celebrex Enterprise is now an association-in-fact consisting of the individuals at Pfizer in
27 charge of running the Celebrex Enterprise, including the sales executives in charge of marketing
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516090.1

1 efforts, executives in charge of advertising and those in charge of developing responses to safety
2 issues. This association in fact meets on a regular basis to guide the operation of the Celebrex
3 Enterprise.

4 228. At all relevant times, each of the Defendants was a knowing participant in the
5 Celebrex Enterprise and benefited from its operation.

6 **Defendants' Use of the U.S. Mails and Interstate Wire Facilities**

7 229. The Celebrex Enterprise engaged in and affected interstate commerce because it
8 engaged in the following activities across state boundaries: The transmission and publication of
9 false and misleading information concerning Celebrex; the sale, promotion and/or distribution of
10 Celebrex; and/or the transmission and/or receipt of sales and marketing literature; and/or the
11 transmission and/or receipt of invoices, statements and payments related to the use or
12 administration of Celebrex.

13 230. Defendants' illegal conduct and wrongful practices were carried out by an array of
14 employees, as well as by consultants and doctors, working across state boundaries, who necessarily
15 relied upon frequent transfers of documents and information, products and funds by the U.S. mails
16 and interstate wire facilities.

17 231. The nature and pervasiveness of the Celebrex Enterprise, which was orchestrated
18 out of the corporate headquarters of Defendants, necessarily required those headquarters to
19 communicate directly and frequently by the U.S. mails and by interstate wire facilities with the
20 various local district managers overseeing the sales force(s), the numerous pharmaceutical sales
21 representatives who, in turn, directly communicated with providers and employees who
22 communicated with the public.

23 232. Many of the precise dates of Defendants' uses of the U.S. mails and interstate wire
24 facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and
25 cannot be alleged without access to these Defendants' books and records. Indeed, an essential part
26 of the successful operation of the Celebrex Enterprise alleged herein depended upon secrecy, and
27 as alleged above, Defendants took deliberate steps to conceal their wrongdoing. However,
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516090.1

1 Plaintiffs can generally describe the occasions on which the RICO predicate acts of mail fraud and
2 wire fraud occurred, and how those acts were in furtherance of the Celebrex Enterprise, and do so
3 below.

4 233. Defendants' use of the U.S. mails and interstate wire facilities to perpetrate the
5 Celebrex Enterprise involved thousands of communications, including *inter alia*:

- 6 a. Marketing materials about Celebrex, which were sent by Defendants to
7 health care providers located across the country;
8 b. Television and print advertisements issued on dozens of occasions;
9 c. Written representations made by Defendants, which were made at least
10 annually and in many cases several times during a single year;
11 d. Documents submitted to the FDA, JAMA and other medical journals
12 designed to conceal the risks of Celebrex and to falsely promote its safety and superiority;
13 e. Written and oral communications directed to U.S. Government agencies that
14 fraudulently misrepresented Celebrex;
15 f. Written and oral communications with health insurers and patients, including
16 Plaintiffs and members of the Class, inducing payments that were made in reliance on the
17 safety and effectiveness of Celebrex;
18 g. Receipts of money sent on tens of thousands of occasions through the U.S.
19 mails and interstate wire facilities – the wrongful proceeds of the Celebrex Enterprise;
20 h. The exchange between Defendants and JAMA (to purchase reprints) and that
21 JAMA never retracted the obviously incomplete and misleading articles, so misleading that
22 the FDA ruled that reprints handed out by drug representatives had to be stamped with “this
23 article contains unsubstantiated comparative claims”; and
24 i. In addition to the above-referenced RICO predicate acts, it was foreseeable
25 to Defendants that others would distribute publications containing false information about
26 the effectiveness of Celebrex through the U.S. mails and by interstate wire facilities.
27 Further, Defendants' corporate headquarters have, in furtherance of the Celebrex
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1 Enterprise, communicated through use of the U.S. mails and by interstate wire facilities
2 with their various local headquarters or divisions. These uses of the U.S. mails include
3 some of the documents referenced in this Complaint.

4 **Conduct of the RICO Enterprise's Affairs**

5 234. Defendants exerted control over their Celebrex Enterprise and, in violation of
6 Section 1962(c) of RICO, conducted or participated in the conduct of the affairs of that RICO
7 enterprise, directly or indirectly, in the following ways:

8 (a) Each Defendant has directly or indirectly controlled the written and televised
9 promotional materials with respect to Celebrex;

10 (b) Each Defendant has directly or indirectly controlled some of the medical
11 literature regarding the effectiveness of Celebrex;

12 (c) Each Defendant has directly or indirectly controlled the goals of the
13 Celebrex Enterprise, *i.e.*, to have Celebrex break the NSAID barrier;

14 (d) Each Defendant has controlled the sales and marketing plans for Celebrex;

15 (e) Each Defendant has directly controlled the creation and distribution of
16 marketing, sales, and other materials used to inform health care providers nationwide of the
17 benefits of using Celebrex;

18 (f) Each Defendant has controlled and participated in the affairs of its Celebrex
19 Enterprise by using a fraudulent scheme to manufacture, market and sell Celebrex; and

20 (g) Each Defendant intended to (and did) distribute publications containing false
21 information through the U.S. mails and by interstate wire facilities.

22 235. The Celebrex Enterprise had a joint decision-making structure, under which each
23 Defendant jointly agreed on how Celebrex was to be promoted and agreed as to how the affairs of
24 the Celebrex Enterprise should be conducted.

25 236. Each of the members of the Celebrex Enterprise had a systemic linkage, because
26 there are contractual relationships, financial ties and continuing coordination of activities between
27 the Defendants and the Celebrex Enterprise. As to each Defendant, there was a common
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